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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 19, 2003, from 8 a.m. to 4:30 p.m. and on June 20, 2003, from 8:30 a.m. to 3 p.m.

Location: Hilton Gaithersburg, Grand Ballrooms A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3514, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 19, 2003, the committee will hear updates on the following tentative topics: Medical Device User Fee and Modernization Act, secure e-mail and electronic submissions, white particulate matter in blood

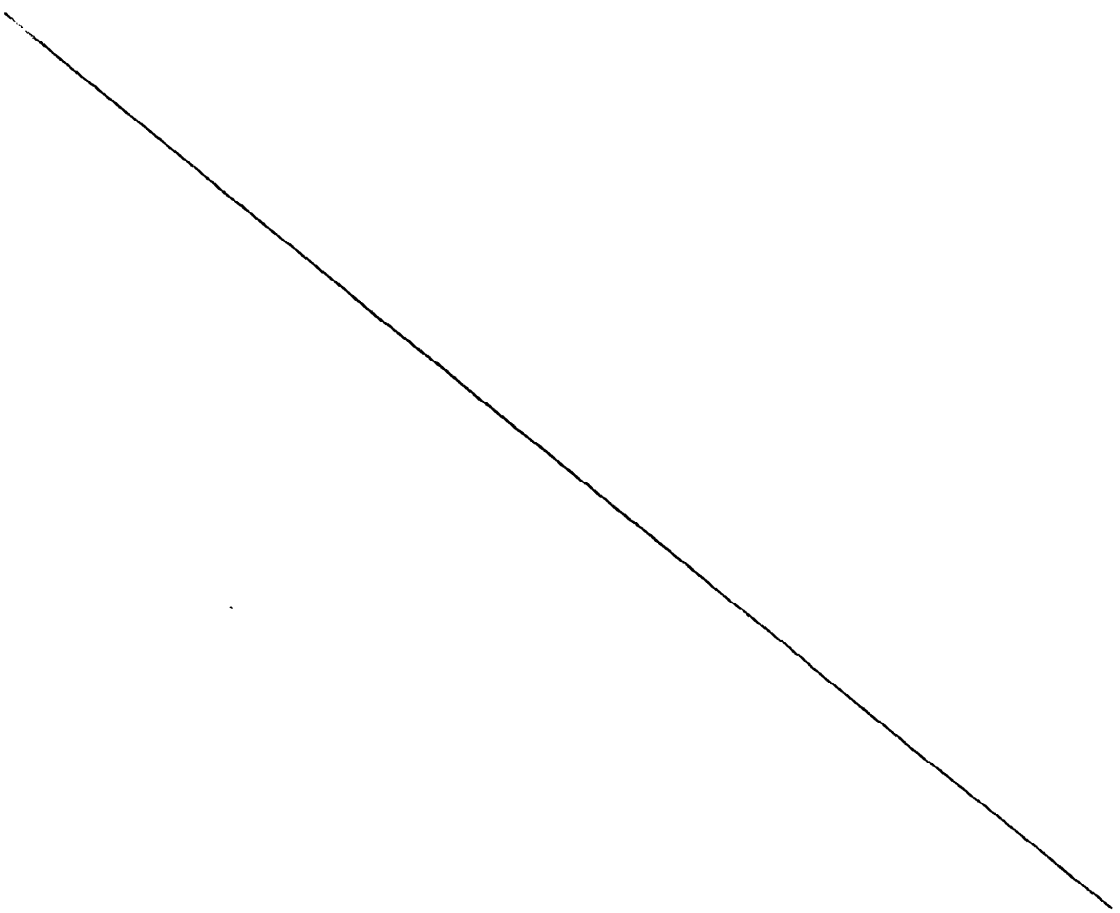
bags, safety reporting requirements for human drug and biological products, and bovine spongiform encephalopathy in Canada. The committee will further hear informational presentations on severe acute respiratory syndrome and West Nile virus. On June 20, 2003, the committee will hear presentations, discuss, and provide recommendations on the topic of recovered plasma. In the afternoon, the committee will hear an informational presentation on the current thinking and indications for use on vaccinia immune globulin intravenous. The background material for this meeting will be posted 1 working day before the meeting under "Blood Products Advisory Committee" on the Dockets Management Branch Web site at http://www.fda.gov/ohrms/dockets/ac/acmenu.htm.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 13, 2003. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:30 a.m. and 2:30 p.m. and 3:30 p.m. on June 19, 2003, and between approximately 9:30 a.m. and 10:30 a.m. and 2 p.m. and 2:30 p.m. on June 20, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 13, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a

disability, please contact Linda A. Smallwood at 301–827–3514 or Pearline K. Muckelvene at 301–827–1281 at least 7 days in advance of the meeting. Persons attending FDA advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA regrets that it was unable to publish this notice 15 days prior to the Blood Products Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Blood Products Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 2, 2003

June 2, 2003.

William K. Hubbard,
Associate Commissioner for Policy and Planning.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

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